

Louisiana Office of Public Health Laboratories	
Test Name	Chikungunya IgM
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86790
Synonyms	CHIK IgM
Brief Description of Test	<p><b>Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.</b></p> <p>This procedure is for the qualitative detection of IgM antibodies against Chikungunya Virus in human serum. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease.</p>
Possible Results	<ul style="list-style-type: none"> <li>• <b>Negative:</b> No detectable IgM antibody; individual does not appear to be infected with Chikungunya virus. The result does not rule out Chikungunya virus infection. An additional sample should be tested within 7 – 14 days if early infection is suspected. Chikungunya PCR can be performed to rule out early acute infection. See CVM.PR.EXM.016 Detection and Identification of Chikungunya Virus by Real time RT PCR</li> <li>• <b>Inconclusive:</b> Samples should be retested before reporting.</li> <li>• <b>Presumptive Positive:</b> Presence of detectable IgM antibody; presumptive infection with Chikungunya virus. The result should be confirmed by plaque reduction neutralization test (PRNT) or by using the latest CDC guideline for diagnosis of this disease. A positive IgM result does not indicate a recent infection because IgM may persist for several months after infection.</li> </ul>
Reference Range	Negative
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	300 µL
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube,

	<p>the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines.</p> <p>Follow the package insert for the collection tube you use.</p> <p>Label specimen with Patient Name and a 2<sup>nd</sup> unique identifier such as a chart number or medical record number. DOB is not considered unique.</p> <p>Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2<sup>nd</sup> patient identifier, gender, date of birth, date of collection, time of collection, onset date, test requested, and submitter's name, address, and contact number.</p> <p>Two unique identifiers <b>MUST</b> be recorded on the tube <b>AND</b> the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place.</p> <p>Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.</p>
Storage and Transport Instructions	<p>Take a venous, whole blood sample.</p> <p>Follow serum specimen collection devices manufacturer instructions for proper collection, separation and storage methods.</p> <ul style="list-style-type: none"> <li>• <i>If specimens are received &gt;7 days from symptom onset, CHIK PCR should be ordered.</i></li> <li>• Specimens may be stored and shipped at 2-8°C for up to 2 days from collection.</li> <li>• Specimens older than 2 days from time of collection should be stored frozen at -20°C or lower and shipped and received in lab frozen on dry ice. If frozen, document the date and time of freezing.</li> <li>• If specimens are to be shipped, they should be packed in compliance with Federal Regulations covering the transportation of infectious agents.</li> </ul>
Causes for Rejection	<p>Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.</p>
Limitations of the Procedure	<ul style="list-style-type: none"> <li>• All reactive samples must be confirmed by PRNT or by using the latest CDC guideline for diagnosis of this disease.</li> <li>• Since this is a presumptive positive assay, the presence of false positive and false negative results must be considered. Cross reactivity with antibodies against Borrelia, CMV and Toxoplasma cannot be excluded.</li> </ul>

	<ul style="list-style-type: none"> <li>• Cross-reactivity with antibodies against other alphaviruses cannot be excluded.</li> </ul>
Interfering Substances	Interference with polyclonal stimulation of EBV infections is likely. In the presence of infectious Mononucleosis (Pfeiffer's Disease, EBV infection) polyclonal stimulation of B lymphocytes can occur. This may result in non-specific reactions in the detection of antibodies of the IgM class. Therefore it is recommended to exclude an EBV infection by differential diagnosis.
References	Package Insert: Genway Anti-Chikungunya Virus IgM Human $\mu$ -capture ELISA Kit
Additional Information	<p>Laboratory evidence of recent chikungunya virus infection is generally accomplished by testing serum or plasma to detect virus, viral nucleic acid, or virus-specific immunoglobulin (Ig) M and neutralizing antibodies. Viral culture may detect virus in the first 3 days of illness; however, chikungunya virus should be handled under biosafety level (BSL) 3 conditions. During the first 8 days of illness, chikungunya viral RNA can often be identified in serum, and RT-PCR is the preferred test (Figure). Chikungunya virus IgM antibodies are generally detectable <math>\geq 4</math> days after onset of illness and can persist for months. Serum collected within 4 days of illness onset may not have detectable IgM antibodies and testing should be repeated on a convalescent-phase sample to rule out infection in those with a compatible clinical syndrome.</p>
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